

# E-MANAGEMENT OF MEDICAL DEVICES IN ITALY

D. Bravar, G. Carlini, A. Cortese, T. dell'Aquila and N. Pangher

ITAL TBS S.p.A., Area Science Park, Trieste, Italy

**Abstract:** Italian Health sector has been experiencing, from several years, a re-organization process, to improve the efficiency of medical devices management by the introduction of new instruments, included internet. In this setting, many companies offer innovative products via web to the health administration, especially for e-procurement. Ital TBS is an Italian Clinical Engineering Services company, managing different biomedical equipment. Moreover it has been managing the Italian Observatory of Prices and Technologies, on behalf of the Italian Ministry of Health and the Friuli Venezia Giulia region. Actually, the national Data Bank consist in more than 70,000 models of medical devices. The know-how acquired by this activity makes Ital TBS the ideal company to create and manage a web portal for biomedical equipment. In order to write a sensible plan of development, we have completed a thorough analysis of the European and Italian Legislation, market analysis and analysis of competitors. The result is that the market does not demonstrate strong reasons to buy on-line, but is heavily interested in finding all possible information on technical specifications, possible configurations and efficient comparison of prices and performances. The ItalTBS choice is developing a web portal to offer high quality information about biomedical devices.

## I. INTRODUCTION

Internet is going to become a very powerful tool for improving the quality of the services offered by a wide typology of companies. Although the public debate has been centred mainly on B2C solution (Business-to-Consumer) the market behaviour shows that the B2B solution (Business-to-Business) will have a wider role.

Italian Health Sector has been experiencing a deep re-organisation process at different levels: the purchase process and management, the financing systems, together with expenditure control and human resources have been re-organised in order to improve the quality of care and cost containment. E-procurement and e-consulting services will have an important role in such a process.

From legislative point of view new rules are necessary to allow the WEB-based purchase processes for the public administration: among the European countries, Italy produced one of the greatest efforts.

The recent hype about e-commerce has driven many companies to offer products for hospitals through the internet. ITALTBS is setting-up a portal for procurement and management of medical devices in order to move its "off-line" services in an "on-line" context.

ITALTBS Spa has a long experience in providing a wide typology of services to health structures. Through its clinical engineering services, the company provides more than 70 hospitals with advanced tools for the biomedical equipment

management:

- Consultancy on the purchase of equipment and medical devices
- Preventive maintenance
- Corrective maintenance
- Inspections of newly acquired equipment
- Periodical check of equipment safety according to European Community rules.
- Performance testing

From the end of 1996, the Italian Ministry of Health financed a 3-years project of the Regional Health Authority of Friuli-Venezia Giulia named "National Observatory of Prices and Technology" (OPT). The aim of this observatory is increase the available instruments to all public health structures providing technical and economic information for a more efficient management of medical devices.

The OPT program, that has been operated by Ital TBS CIVAB in the framework of an agreement between the Regional Health Authority and the Area Science Park, has developed the following products:

1. Technical bulletins on 36 different categories of biomedical equipment available on the national market;
2. A national Data Bank and a national Coding System of medical equipment and devices;
3. A monitoring system of medical equipment and devices (diagnostic reagents, X-ray films, hemodialysis filters, pacemakers, angiographic catheters, implantable devices) purchase prices, based on data collected from the Italian Regions;
4. Remote consultation (via Internet) of technical information and purchase prices of medical devices in the National Health System.

Within this project the company has managed the National Data Bank of Biomedical Equipment whose archives contain technical and commercial data on about 70,000 different models of medical equipment and devices such as pacemakers, prostheses and diagnostic reagents.

## II. METHODOLOGY

To create a model for an "Electronic Office for Medical Devices management and procurement", the Italian Healthcare system must be analyzed. The Italian Healthcare system is managed by public administration, based on a strong discipline on purchase practices. A lot of European, national and regional regulations bind to make tenders in order to purchase medical devices. There are different rules depending on the value of the items: over 200.000 Euro an European tender must be performed, while usually under this value it's possible to make national tenders.

## Report Documentation Page

<b>Report Date</b> 25 Oct 2001	<b>Report Type</b> N/A	<b>Dates Covered (from... to)</b> -
<b>Title and Subtitle</b> E-Management of Medical Devices in Italy		<b>Contract Number</b>
		<b>Grant Number</b>
		<b>Program Element Number</b>
<b>Author(s)</b>	<b>Project Number</b>	
	<b>Task Number</b>	
	<b>Work Unit Number</b>	
<b>Performing Organization Name(s) and Address(es)</b> ITAL TBS S.p.A Area Science Park Trieste, Italy		<b>Performing Organization Report Number</b>
<b>Sponsoring/Monitoring Agency Name(s) and Address(es)</b> US Army Research, Development & Standardization Group (UK) PSC 803 Box 15 FPO AE 09499-1500		<b>Sponsor/Monitor's Acronym(s)</b>
		<b>Sponsor/Monitor's Report Number(s)</b>
<b>Distribution/Availability Statement</b> Approved for public release, distribution unlimited		
<b>Supplementary Notes</b> Papers from 23rd Annual International Conference of the IEEE Engineering in Medicine and Biology Society, October 25-28, 2001, held in Istanbul, Turkey. See also ADM001351 for entire conference on cd-rom., The original document contains color images.		
<b>Abstract</b>		
<b>Subject Terms</b>		
<b>Report Classification</b> unclassified	<b>Classification of this page</b> unclassified	
<b>Classification of Abstract</b> unclassified	<b>Limitation of Abstract</b> UU	
<b>Number of Pages</b> 3		

Moreover depending on the particular region in Italy, below a certain limit (ranging from 5000 to 25000 Euro) “private bargaining rules” are performed, which allow an administrator to buy a particular device after having received offers from different suppliers (almost three offers).

Public commissions, composed by administrators, medical doctors and technical consultants (typically clinical engineers or healthcare consultants), judge the technical performances and the economic conditions offered by the suppliers. The technical performances are based on the clinical needs of the physicians, on the amount of activity for the particular equipment/device and on the funding available to the hospital. The technical consultants can define a minimum set of technical specifications which have to be satisfied and result in a “go – no go” answer: the cheapest bid would then win the tender. Another possibility is to define a complete set of technical specifications with a related weight parameter, which could be used to assign a score to the technical offer: the combination of technical score and cost would then serve as the parameter determining the winning bid.

During last years one of the core activities of ITALTBS has been to deliver the consulting services for the purchase commissions and this create the starting point to create a model of the “Electronic Office for Medical Devices Management”. An internet solution could offer to the administrations a new, rapid and practical method of publishing the technical specifications together with the economic conditions and calling for bids available to all interested suppliers.

Actually the average time needed to organize and conclude a procurement process range from 10 to 18 weeks: the first 2 to 4 weeks are spent in defining the technical and economic specifications for the devices to be purchased, while the following period is used to receive the bids and analyse results. Supplier provision offices always receive technical specifications just in time to prepare an offer and often they work in a little time.

In this terms also suppliers would be facilitated because they could read immediately on line technical specifications, download all documentation and send offers in digital format, facilitating also the analysis of documentation.

The whole process time could be reduced by as much as 50% with a substantial impact on the costs of the procedure.

At the end, thank to the new rules, it would be possible that hospital administrations can purchase medical devices as a private administration. Web portal is designed to offers an e-market place in which it would be possible the organization of inverse auctions, where the technical specifications could serve as a pre-qualification and the bidders could make their economic offers on-line, lowering the price in order to win the bids. There will be a transact section to submit the proposal, publish auction and create procurement groups.

Many new players have entered the market of e-commerce in the healthcare sector, and normally only little information is available about the results of the initiatives. About 15 competitors were identified in Europe: most of them are directed to a national market, while about three are targeting an European audience. An important target of the analysis

was to find financial information: are companies, offering e-commerce solutions for the purchase of biomedical equipment, successful? Data and comments are available only about companies listed on stock exchanges.

### III. RESULTS

The model of the “Electronic Office for Medical Devices Management and Procurement ” is based on the transfer of the off-line core competencies of ITALTBS in an on-line context: the customer will be able to obtain the technical specifications of the equipment, after answering a set of questions about his clinical needs and more generally about his activity.

In particularly, the available services (fig.1) are listed below:

- Free access information
- On line consulting
- Auction on line

At the first level, principle of operation for the most important medical equipment, the most interesting news from the healthcare field, discussion forums on topics of great interest in this field, workshop and congress, news (product and actions) from manufacturers are available.

To access the second level, the customer needs to be registered as a client. In this level he finds detailed technical features and data for each product and informative sheets on biomedical equipment.

In this level, the customer is guided to the definition of technical specification of the device needed, by a guided list of questions. The portal shows all the commercial products and the medium price for this configuration, and list the minimum technical specifications requirement.

On demand, the specifications can be included into a specific document necessary for a tender of public administration.

The third level is the organization of inverse auctions, where the technical specifications could serve as a pre-qualification and the bidders could make their economic offers on-line, lowering the price in order to win the bids.

The complete model of the web portal for the “Electronic Office for Medical Devices Management and Procurement” is described in Fig. 2.

### IV. DISCUSSION

The Procurement Officers have expressed doubts about concluding all the acquisition procedures on-line, through auctions. For the moment, in the acquisition of biomedical equipment and devices, particularly if characterized by high technology content and important clinical effects, a commission where also medical and technical experts are present, is viewed as necessary. Only the commission can sanction which equipment fits best the clinical, technical and economic conditions set by the hospitals. Besides, some critical points have been found, mainly due to the organization complexity and the heterogeneity of the

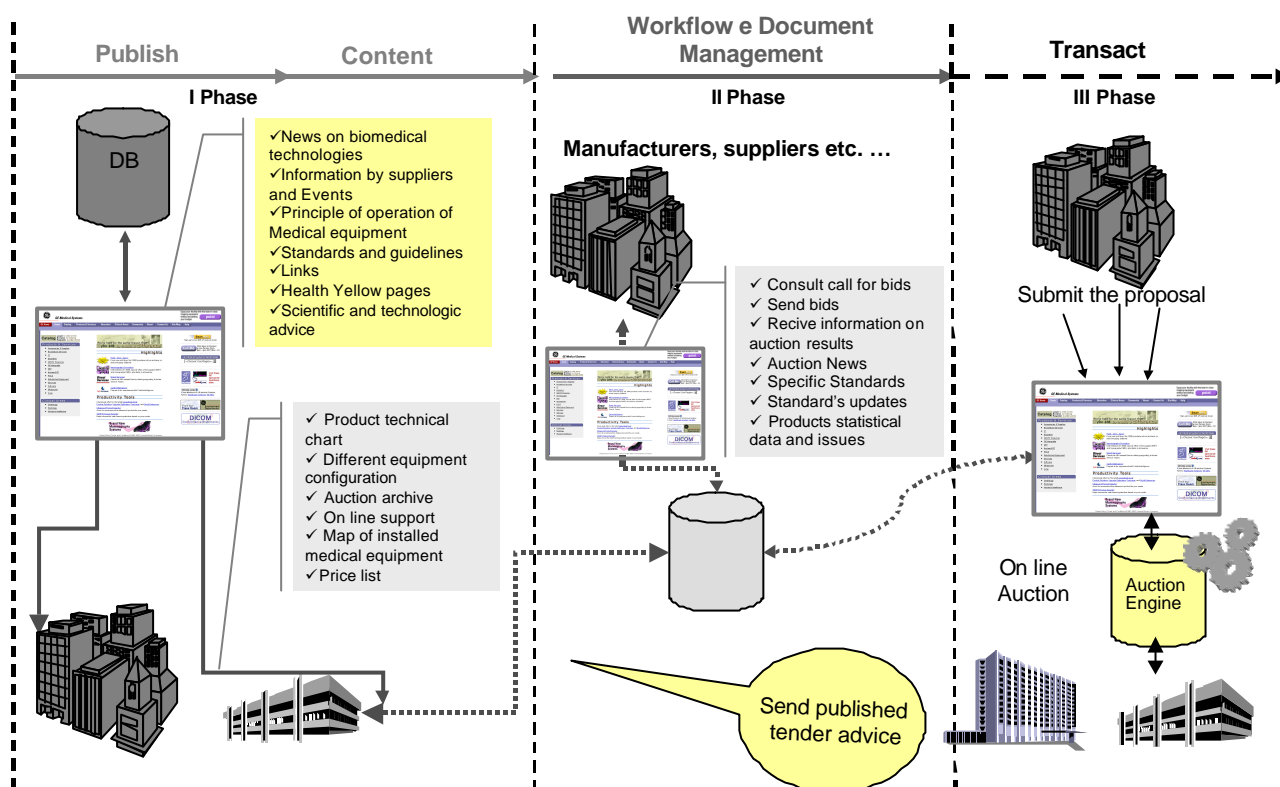


Figure 2: Description of "Electronic Office for Medical Devices Management and Procurement".

purchase processes of health structures.

On the other side the legislation allows free movement to the hospitals below the threshold of 200.000 Euro: this could lead to the possibility of closing agreements with the single hospitals to set up particular acquisition procedures. The legal framework is therefore not completely clear, also because e-commerce practices are still in their infancy. There is room though for what are called experimentation: special procedures that hospitals or regional health authorities can follow in order to test new procedures.

## V. CONCLUSION

Although the market does not demonstrate strong reasons to buy on-line, it seems heavily interested in finding all possible information on technical specifications, possible configurations and efficient comparison of prices and performances. To offer on-line services to the hospital administration, the best choice may be starting from make available via web high quality information about biomedical devices in Italy and in Europe. Only in a second moment, depending on the development of the market conditions, will be possible the creation of a full e-marketplace with a on-line auction activity.

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